PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 : A23P 1/02, A23C 9/18 A23L 1/305, 1/308

A1

(11) International Publication Number: WO 86/ 03380

(43) International Publication Date: 19 June 1986 (19.06.86)

(21) International Application Number: PCT/EP85/00676

(22) International Filing Date: 5 December 1985 (05.12.85)

(31) Priority Application Number: 23966 A/84

(32) Priority Date: 10 December 1984 (10.12.84)

(33) Priority Country: IT

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(81) Designated States: AT, CH, DE, DK, FI, GB, JP, LU, NL, NO, SE, US.

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: DIETETIC COMPOSITIONS

(57) Abstract

Dietetic compositions in form of chewable tablets prepared by compression or extrusion, comprising, variable amounts of proteins of various kinds, aminoacids, carbohydrates, lipids, vitamins, salts, swelling and flavouring agents, according to the intended use. The compositions according to the invention are useful as hypocaloric meal substitutes and also as diet integrators in sports.

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DIETETIC COMPOSITIONS

The present invention relates to dietetic compositions in the form of chewable tablets, prepared by compression or extrusion of the components of said dietetic compositions.

It is common dietetic practice to treat over-weight persons with dietetic compositions which allow to supply a limited and controlled caloric contribution and which are able to replace one or more of the usual daily meals.

The limitation of the assumed calories is considered today as one of the better therapeutic means for the treatment of obesities of various origin, without having to resort to the use or abuse of anorexing medicines whose possible side-effects are well known.

The limited caloric contribution is secured by the administration of different compositions containing mixtures of easily resorbable proteins, protein lysates, carbohydrates and l-α-aminoacids.

Frequently, to the above referred dietetic compositions natural or semisynthetic polymers are also added, e.g. guar gum, sodium carboxymethylcellulose, pectins, mucilages, i.e. substances which are easily swollen when in contact with liquids.

The addition of such swelling agents to the dietetic compositions is based on the principle that, when ingested, the polymers contained undergo a swelling process in the stomach, which is able to induce in the user a surfeit feeling sufficient to make useless to resort to

normal nutrition.

The above referred dietetic compositions are generally presented in the form of powders which are to be swallowed after dispersion into liquids, generally water, milk or other hypocaloric aqueous beverages. In any case their ingestion does not occur in the solid state but always by swallowing of finely divided aqueous suspensions or in the form of diluted mushes prepared at the time of their use.

Accordingly, the user needs to have at his disposal the diluting liquid and suitable containers as glasses or shakers for their preparation.

Additionally, small tablets containing exclusively said swelling polymers are also available: in this case, obviously, no nutritional or caloric contribution is given; instead, an attempt is made to induce an anorexing effect by virtue to the surfeit feeling which is caused by the swelling in the inner of the stomach.

Now it has been found that it is possible to obtain dietetic compositions which have the following advantages when compared with known formulations:

- a greater practicality of use because they do not require the simultaneous intake of liquids;
- a better psychological satisfaction of the user who is keener to accept, as a meal substitute, a composition requiring in any case a chewing action, instead of ingesting a tablet or a suspension, with advantageous effects also on that physiological processes which are frequently a consequence of chewing itself (gastric juice secretion, etc.);

- the possibility to mask the unpleasant taste of some components;
- the preservation of the original qualities of thermally labile components (proteins, carbohydrates) by virtue of the particular preparation process employed.

The compositions according to the invention are in form of chewable tablets having a weight from 1 to 30 g, preferably from 5 to 10 g, and comprise, according to the intended use, variable amounts of proteins, aminoacids, protein lysates, carbohydrates, lipids, vitamins, carnitine or derivatives, salts, milk ferments, swelling agents and flavouring agents. Special examples of swelling agens comprise sodium carboxymethylcellulose, guar gum, pectin, alginic acid.

The new formulations, namely the chewable tablets, are also useful to prepare dietetic compositions which are to be employed in nutritional and energetic integration in sport activities and/or to be used as dietetic integrators by subjects which are on special diets.

In these cases, too, the new dietetic formulations are in agreement with the scopes of the invention since they show a practical and extemporaneous use thus allowing the user to obtain at the same time a psychological, olfactory and gustatory satisfaction. The form, the size and the weight of the tablets are in no way critical and should be adapted to allow an easy chewing action.

For the use as nutritional and energetic integrators in sports, the tablets should preferably contain rapidly resorbable carbohydrates (dextrose, fructose, etc.), aminoacids, proteins, carnitine and optionally

salts and vitamins.

For the use as dietetic integrators for subjects which are on special diets, the tables should contain mainly aminoacids or, as a general rule, the components which are insufficient or lacking in the prescribed diets. When aminoacids or other substances of unpleasant taste should be present (leucine, methionine, cysteine), they can be used in microincapsulated form or covered wih suitable membranes which allow to mask the taste during chewing and dissolve when in contact with gastric juices.

For the use as hypocaloric meal-substituting food, the said components can be joined with known swelling agents as guar flour, pectin, sodium carboxymethylcellulose etc., to produce chewable tablets which can be directly ingested, without resorting to previous dispersion in glasses, shakers or other containers as required for known products.

However, the prolonged use of hypocaloric dietetic formulations could compromise the intestinal environment. Accordingly, it is greatly desirable to include in the hypocaloric dietetic formulations special components as milk ferments, e.g. Thermobacterium bulgaricum, Streptococcus thermophylus, Lactobacillus acidophilus which can contribute to the preservation of the intestinal bacterial flora. This is greatly desirable when a reduced intake of normal food is present owing to dietetic reasons. It is preferred to use the active milk ferments in amounts from 10^4 to 10^{12} microorganisms/g of final granulate, amounts from 10^8 to 10^9 microorganisms/g being highly preferred.

The presence of active milk ferments in the granu-

lates is not, by itself, inconsistent with other components of the formulations according to the invention, provided that the moisture content of the final hypocaloric dietetic composition is low. This allows to avoid an uncontrolled growth of the microorganism with the aim to maintain a constant count and to achieve an optimal preservation of the granulate according to the invention. It has been found that this effect can be obtained when the granulate is dried before its compression and final extrusion, under controlled temperature and aeration conditions. Optimal conditions are, e.g., the drying in a fluidized bed and/or in a forced air circulation oven at 30-40°C and at a filtered sterilized air flow from 0.5 to 20 m^3/min.

To this aim, in the preparation of the granulates, it is employed powdered lean milk already containing active milk ferments or single liophilized milk ferments are added to the normal granulates already described.

The advantages of the tablets according to the invention are achieved by virtue of their special preparation process, which is a further scope of the present invention.

The preparation procedure of the tablets according to the invention comprises the compression of a mixture of the different components on a rotary or eccentric apparatus or the extrusion through a die in which the mixture is forced under very high pressure by a screw.

Since the components in the mixture are not subjected to melting or extreme heating, their denaturation is avoided and an easily digestible final product with an

high nutritional value is accordingly obtained.

The percentages of the different components in the chewable tablets are not critical and allow to give a balanced nutritional and energetic contribution which is suited for the intended use, as is easily established by people skilled in the art.

The tablets according to the invention can be of such shape and size that they can be easily consumed in a single or multiple administration, their consistency being such that a comfortable chewing action is always secured.

The following not limitative examples are given to further illustrate the present invention.

EXAMPLE 1

Cocoa flavourized hypocaloric meal substitute

Powdered lean milk	kg	8.000
Whole milk proteins (Refit$^{(R)}$)	kg	12.000
Fructose	kg	7.500
Cocoa butter	kg	3.500
Guar flour	kg	0.500
Cocoa	kg	1.500

Preparation procedure

Powdered lean milk, Refit$^{(R)}$, fructose, guar flour and cocoa are sieved with a 100 mesh/cm^2 stainless steel sieve. Thereafter they are introduced into a quick standing granulator and mixed for 5 min. at a 100 r.p.m. speed.

To the mixture, under continuous stirring, the cocoa butter which had been previously melted on a water bath thermostated at 50°C, is added.

When homogeneous, the mixture is moistened with 5.5 l of purified water; the moistening operation, too, is

performed in the standing quick granulator, the mass being stirred by horizontal blades which rotate at 100 r.p.m. and by knives rotating at right angles with respect to the blades at 80 r.p.m.

The granulate is dried in a fluidized bed desiccator with air thermostated at 60°C for 20 min.

The dried granulate is sieved with an oscillator sieve having stainless steel meshes (net mesh separation 1.2 mm).

The granulate is compressed with an eccentric compressing device, model 4R-Ronchi, under a 2 ton/cm^2. pressure to produce 4,000 rectangular tablets weighing about 8 g and having 23 x 62 x 6 mm size.

Four tablets, corresponding to a total of 120 kcal, are packed in aluminium-polyethylene envelopes. An envelope is recommended as a hypocaloric meal substitute.

EXAMPLE 2

Hypocaloric meal substitute integrated with aminoacids

L-Leucine	kg 2.000
L-Valine	kg 2.000
L-Isoleucine	kg 1.000
Powdered lean milk	kg 8.000
Whole milk proteins (Refit$^{(R)}$)	kg 12.000
Fructose	kg 7.500
Cocoa butter	kg 3.500
Guar flour	kg 0.500
Cocoa	kg 1.500

Preparation procedure

The preparation is similar to that described in Example 1, the granulate being compressed under a 3

ton/cm^2 pressure to obtain 4,000 tablets weighing 9.50 g and having 2 x 6 x 0.5 size. Four tablets are collected in an aluminium-polyethylene envelope and an envelope is recommended as integrated hypocaloric meal substitute.

EXAMPLE 3

Hypocaloric meal substitute integrated with vitamins and aminoacids

L-Leucine	kg	2.000
L-Valine	kg	2.000
L-Isoleucine	kg	1.000
Powdered lean milk	kg	8.000
Whole milk proteins (Refit$^{(R)}$)	kg	12.000
Fructose	kg	7.500
Cocoa butter	kg	3.500
Guar flour	kg	0.500
Cocoa	kg	1.500
Vitamin A palmitate	g	2.500
Vitamin E	g	7.000
Vitamin B_1 mononitrate	g	0.300
Riboflavine	g	0.500
Vitamin B_6 hydrochloride	g	0.500
Nicotinamide	g	3.300
Calcium pantotenate	g	2.600
Folic acid	g	1.100
Ascorbic acid	g	15.000.

Preparation procedure

The preparation is similar to that described in Example 1. Vitamins are dispersed in the dried granulate before its compression into tablets.

According to the procedure of Example 2, tablets of

a 9.5 g weight are obtained. Four tablets are collected in an aluminium-polyethylene foil envelope each envelope, being presented as vitamin integrated meal substitute.

EXAMPLE 4

Vanilla flavoured hypocaloric meal substitute

Powdered lean milk	kg 15.000
Fructose	kg 10.000
Glucose	kg 5.000
Cocoa butter	kg 3.000
Guar flour	kg 0.500
Vanilla flavour	kg 0.300

Preparation procedure

The preparation is similar to that described in Example 1. The vanilla flavour is dispersed into the dried granulate before its compression into tablets.

According to the procedure of Example 1, 4,000 tablets weighing 8.04 g are obtained. Four tablets are collected in an aluminium-polyethylene foil envelope, each envelope being presented as hypocaloric meal substitute.

EXAMPLE 5

Dietetic integrator (in fatiguing conditions)

L-Leucine	kg 2.000
L-Valine	kg 2.000
L-Isoleucine	kg 1.000
Milk albumin	kg 4.000
Glucose	kg 10.000
Fructose	kg 10.000
Saccharose monopalmitate	kg 0.200
Citric acid	kg 0.600

Orange flavour	kg	0.200.

Preparation method

The preparation is similar to that described in Example 1. Saccharose monopalmitate and citric acid are dissolved in the purified water used for the granulation of the powder. Orange flavouring is dispersed in the dried granulate before its compression in tablets. After a compression of 2 ton/cm^2 there are produced 4,000 tablets weighing 7.5 g.

The tablets are separately packed in aluminium-polyethylene strip packages for single or multiple use, depending on the condition, e.g. of a sportsman.

EXAMPLE 6

Cocoa flavourized hypocaloric meal substitute

Powdered lean milk	kg	8.000
Whole milk proteins (Refit(R))	kg	12.000
Fructose	kg	7.500
Cocoa butter	kg	3.500
Sodium carboxymethylcellulose	kg	0.700
Cocoa	kg	1.500

Preparation procedure

The preparation is similar to that described in Example 1. 4,000 Tablets weighing 8.3 g are obtained.

EXAMPLE 7

Hypocaloric meal substitute with methionine

Microincapsulated L-leucine(*)	kg	2.000
Microincapsulated L-valine(*)	kg	2.000
Microincapsulated L-isoleucine(*)	kg	1.000
Microincapsulated L-methionine(*)	kg	0.210
Powdered lean milk	kg	8.000

Whole milk proteins	kg	12.000
Fructose	kg	7.500
Cocoa butter	kg	3.5
Guar flour	kg	0.5
Cocoa	kg	1.5
Vitamin A palmitate(**)	g	3.25
Vitamin E(**)	g	7.21
Vitamin B_1 mononitrate(**)	g	0.39
Riboflavine(**)	g	0.65
Vitamin B_6 hydrochloride(**)	g	0.65
Nicotinamide	g	3.3
Calcium pantothenate	g	2.6
Folic acid	g	1.1
Ascorbic acid	g	15.000

(*) Microincapsulated in 5% ethylcellulose (commercially available);

(**) Microincapsulated in 30% ethylcellulose (commercially available).

Preparation method

The preparation is similar to that described in Example 1. The microincapsulated or not microincapsulated vitamins are dispersed in the dried granulate before its compression in tablets. The compression is performed by using dies which produce tablets of 62 x 35 x 7.8 mm size, weighing 18.6 g. Two tablets are joined in an aluminium-polyethylene foil envelope. Each package is presented as meal substitute integrated with methionine and vitamins.

EXAMPLE 8

Dietetic integrator (for sportsmen)

L-Leucine	kg	2.000

L-Valine	kg	2.000
L-Isoleucine	kg	1.000
Lactalbumin	kg	4.000
Glucose	kg	10.000
Fructose	kg	10.000
Saccharose monopalmitate	kg	0.2
L-Carnitine hydrochloride	kg	1.000
Banana flavour	g	160.

Preparation method

The preparation is similar to that described in Example 1. Saccharose monopalmitate is dissolved in the purified water used for granulating the powders.

Banana flavour is dispersed in the dried granulate before its compression in tablets. After the usual compression at 2 ton/cm^2 with a 25x 85 x 4 mm die, 4,200 tablets weighing 7.2 g are obtained. The tablets are packaged in aluminium-polyethylene strip packages, separated from each other for single or multiple use, depending on the sportman's need.

EXAMPLE 9

Hypocaloric meal substitute with active milk ferments

Lean milk with active ferments	kg	11.000
Refit$^{(R)}$	kg	12.000
Fructose	kg	7.500
Cocoa butter	kg	3.500
Guar flour	kg	0.500
Cocoa	kg	1.500

Preparation method

Powdered lean milk with active ferments, Refit$^{(R)}$, fructose, guar flour and cocoa are sieved with a 100 me-

sh/cm^2 stainless steel sieve. Thereafter they are introduced into a standing quick granulator and mixed for 5 minutes at 100 r.p.m.

To the mixture, cocoa butter, which was previously melted on a water bath thermostated at 50°C, is added under stirring.

When homogeneous, the mixture is moistened with 5.5 l of purified water; the moistening operation, too, is performed in the standing quick granulator, the mass being stirred by horizontal blades which rotate at 100 r.p.m. and by knives rotating at right angles with respect to the blades at 80 r.p.m. The granulate is dried in a fluidized bed desiccator with air thermostated at 35°C for 30 min.

The dried granulate is sieved with an oscillating sieve having stainless steel meshes (net mesh separation 1.2 mm).

The granulate is compressed with an eccentric compressing device, model 4R-Ronchi, under a 2 ton/cm^2 pressure to produce 4,000 rectangular tablets weighing 9 g and having 23 x 62 x 7 mm size. Four tablets correspond to 190 kcal total and are packed in aluminium/polyethylene envelopes. Each package is recommended as hypocaloric meals substitute with active milk ferments.

EXAMPLE 10

According to the method of Example 9 banana flavouring (0.3 kg) can be substituted for cocoa in the granulate. Similarly, by following essentially the procedures of examples 2, 3 new granulates can be produced containing active milk ferments by replacing their lean milk content with lean milk containing active milk ferments and/or by

adding liophilized active milk ferments to the mixtures already described, provided that after the active milk ferments addition the granulates are dried according to the method of Example 9, at a temperature of 35°C.

EXAMPLE 11

Powdered milk	kg 8.0
Liophilized milk ferments corresponding to 4×10^{13} microorganisms	
Fructose	kg 4.0
Vanilla flavouring	kg 0.2.

Powdered milk and fructose are granulated with 2 l of purified water according to the production method of Example 1. The liophilized milk ferments and the vanilla flavouring are added to the dried granulate. The granulate is compressed in tablets yielding 4;000 tablets weighing 3 g.

CLAIMS

1. Dietetic compositions characterized by comprising, variable amounts of proteins, aminoacids, carbohydrates, lipids, vitamins, salts, milk ferments, swelling agents and flavouring agents, according to the intended use, said dietetic compositions being in form of chawable tablets.

2. Compositions according to claim 1, suitable for use as dietetic and energetic integrators in sports, characterized by containing proteins, carbohydrates and aminoacids.

3. Compositions according to claim 1, suitable for use as hypocaloric meal substitutes, characterized by containing sodium carboxymethylcellulose, pectin, alginic acid, guar flour associated with proteins, carbohydrates and aminoacids.

4. Compositions according to claim 1, suitable for use as dietetic integrators, characterized by containing aminoacids.

5. Compositions according to claims 1-4, wherein the components having un unpleasant taste are microincapsulated or covered with a membrane which dissolves when in contact with gastric juices.

6. Compositions according to claim 1, suitable for use as hypocaloric meal substitutes, comprising powdered lean milk, whole milk proteins, fructose, guar flour, cocoa and cocoa butter.

7. Compositions according to claim 6, suitable for use as hypocaloric meal substitutes, additionally comprising

l-leucine, l-valine and l-isoleucine in a weight ratio of approximately 1:1:0.5.

8. Compositions according to claim 7, additionally comprising vitamins as Vitamin A, E, B_1, riboflavine, Vitamin B_6 hydrochloride, nicotinamide, calcium pantothenate, folic acid, ascorbic acid.

9. Compositions according to claim 1, suitable for use as dietetic integrators in fatiguing conditions comprising, l-leucine, l-isoleucine and valine in a weight ratio of approximately 1:1:0.5, milk albumin, fructose, and optionally flavouring agents, citric acid and saccharose monopalmitate.

10. Compositions according to anyone of the previous claims also comprising carnitine and derivatives.

11. Compositions according to anyone of the previous claims also comprising active milk ferment between 10^4 and 10^{12} microorganisms/g of final granulate.

12. The method for the preparation of the compositions of claims 1-6, wherein the mixed components are compressed on a rotary or eccentric apparatus or extruded through a die in which the mixture is compressed by a screw.

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 85/00676

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [5]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 23 P 1/02; A 23 C 9/18; A 23 L 1/305; A 23 L 1/308

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 23 L A 61 K

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	US, A, 4220666 (M. FIELDS) 2 September 1980, see claim 1; column 3, line 58 - column 5, line 30; examples	1,2,4,12
X	EP, A, 0059535 (MENLEY & JAMES LABORATORIES) 8 September 1982, see claims 1-12; examples 1-3	1,12
X	EP, A, 0028374 (BIOTEST-SERUM-INSTITUT) 13 May 1981, see example 13; page 13, lines 13-15	1,12
X	EP, A, 0009219 (W. MUNK) 2 April 1980, see claim 1; example 2	1,11
X	US, A, 3360374 (C. BARR) 26 December 1967, see claims 1-6; column 3, lines 20-35; column 4, lines 1-6; examples	1,2
X	EP, A, 0120705 (NABISCO BRANDS) 3 October 1984, see claim 1; examples 1,2	1
X	US, A, 4042688 (A. GANS) 16 August 1977, see claims 1-4; examples 1-6	1,2 ./.

* Special categories of cited documents: [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
19th March 1986	15 APR 1986
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	M. VAN MOL

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
X	DE, A, 2824977 (BIOCHEMISCHE GESELLSCHAFT) 13 December 1979, see claims 1,2,3; page 4, alinea 3; page 5, alinea 2 --	1
A	EP, A, 0127287 (NABISCO BRANDS) 5 December 1984, see claims 1-5; examples 1,2 --	3
A	Patents Abstracts of Japan, volume 5, no. 132 (C-68)(804), 22 August 1981 & JP, A, 5668374 (JIYUN SAWADA) 9 June 1981, see abstract	1,7,9
